Quality Systems: Protection Against Litigation

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QA at the Irish Equine Centre

- Dedicated equine diagnostic laboratory
- Traditional – in-house methods
- Limited access to commercial assays
- GLP for commercial studies (1996-2017)
- ISO17025 initially for contract work in other species (2004 - present)

Pushback

- Expense – designated QA staff, fees etc
- Huge time commitment across organisation
- Culture change – academic, classical
- Concern that would inhibit innovative
- Resentment - QA personnel and inspectors
- Imposition (OIE, contracts etc.)

Becoming a QA Convert

- Realisation of benefit to laboratory manager
- Justification to administrators for investment
- Staff accountability and ownership, direct influence
- Timely detection of areas that require improvement
- Minimises errors and delays
- Inspections help introduce improvements and prevent “team error”
- Responding to Client complaints (legitimate or spurious)

Ongoing investment in QA is fully recompensed in a crisis

- Records documenting what should have happened (SOPs)
- Records documenting exactly what happened (worksheets etc). Hugely important as may be a time lapse before the complaint.
- Human error can be due to flawed procedure or deficiency in execution

Insurance companies

- Accreditation promotes trust in test reliability, operational performance and competence.
- Formal recognition that laboratory is competent.
- Focus of the courts is on the culture of the organisation, handling of the sample, staff, equipment, reagents, reporting system

Evidence of Competence

- Documented success in proficiency tests
- Interlaboratory comparisons
- Procedures validated internationally
- Use of international standards
- Calibrated equipment
- Staff qualifications and training
- Regular staff competency tests, CPD

Delayed diagnosis complaints

- Assist clinician with sample submission
- Timelines for results……. be careful
- Document what you do…..
- SOPs re sample rejection, incomplete submission forms, repeat testing etc.
- Telephone records

Misdiagnosis complaints

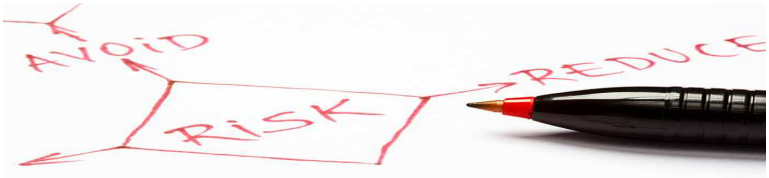
- Good communication frequently avoids litigation
- Not always about financial compensation
- Require explanation
- Demonstrate traceability and explain procedures
- Human error
- Apologise if appropriate
- Commitment to excellence
- Corrective action

False accusations

- Incorrect animal identification
- Report tampering – fraud
- Storage of samples essential

Risk Reduction

- Definition of roles and responsibilities along entire chain
- Pre-analytics and post-analytics
- Interpretive comments and clinical advice
- Expertise of veterinary professionals
- Keep copies of fax records or other confirmation of delivery
- Management must commit to impartiality
- Eliminate all falsification
- No information in the record or equipment used should be changed after the fact



- "No blame culture"
- Recognise, track and fix laboratory and system errors
- Initiatives across the organisation – inclusive responsibility
- Identify predisposing factors behind errors
- Challenge antiquated practices and methodologies
- Propose that outdated equipment be replaced with newer, more reliable technology.
- SOPs and WS should be usable living documents

Accreditation ensures quality for the client, protection for the laboratory and security for the professional.

Thank you